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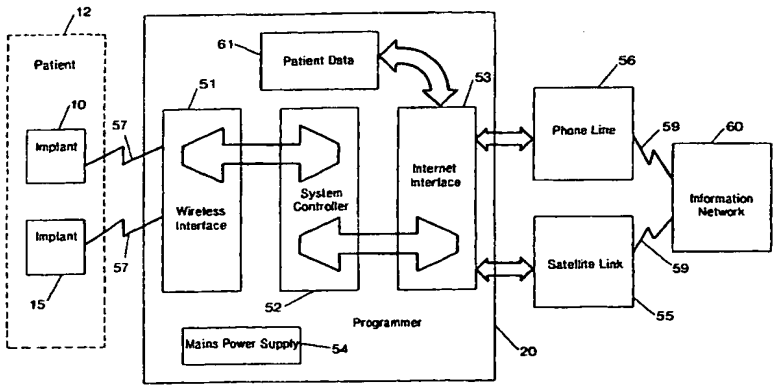
(54) Title: RESPONSIVE MANUFACTURING AND INVENTORY CONTROL



(57) Abstract: A medical device production and supply information management system synchronous with manufacturing, planning and scheduling, product consumption forecast, and component purchase to enable just-in-time inventory control at the manufacturing facility, vendor stocks, material/product tracking, distribution and shipping management to thereby reduce inventory at all points in the product manufacturing, distribution/delivery chain. The system is implemented using a preferably Web enabled information network and data communications with a programmer. The programmer provides access to product information, specification and related data for implanted medical devices from which build-to-order and build-to-replenish commands are issued to the manufacturing center. The system is interactive within the consumption management system that is integrally and seamlessly connected with patients, hospitals, sales offices and related information hubs including manufacturing facilities. The invention enables management of inventory levels of medical devices through the interactive information management system by accurately accounting for inventory stored in sales offices, distributors and sales representatives, as well as implanting institutions to ensure that all centers have appropriate and adequate stock that is replaced on just-in-time basis under the build-to-replenish scheme.

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The short range of conventional device telemetry is itself viewed as unduly limiting the communication of information over a long distance. In the medical monitoring field, longer range, continuously accessible telemetry has been sought and systems for doing so have been proposed. In U.S. Pat. No. 5,113,869, *Implantable Ambulatory Electrocardiogram Monitor* to Nappholz, et al, for example, an implanted ambulatory ECG patient monitor is described that is provided with longer range telemetry communication with a variety of external accessory devices to telemeter out alarm signals and ECG data and to receive programming signals. The high frequency RF signals are encoded, including the implanted device serial number, to ensure that the communication is realized only with the proper implanted device and that it is not misprogrammed.

A remote, external programmer and analyzer as well as a remote telephonic communicator are also described that may be used in addition to, or alternately to, the personal communicator alarm and/or the full disclosure recorder. The programmer and analyzer may operate at a distance to the implanted AECG monitor to perform programming and interrogation functions. The implanted AECG may automatically transmit a béacon signal to the programmer and analyzer to initiate an interrogation function to transmit data to the programmer and analyzer on detection of an arrhythmia or a malfunction of the implanted AECG monitor detected in a self-diagnostic test. Or by setting a timer in the personal communicator alarm, the implanted AECG monitor may be automatically interrogated at preset times of day to telemeter out accumulated data to the telephonic communicator or the full disclosure recorder. The remote telephonic communicator may be part of the external programmer and analyzer and is automatically triggered by the alarm or data transmission from the implanted AECG monitor to establish a telephonic communication link and transmit the accumulated data or alarm and associated data to a previously designated clinic or physician's office through a modem.

A similar hand-held interrogator for an implanted pacemaker-cardioverter-defibrillator device is disclosed in U.S. Pat. No. 5,336,245, *Storage Interrogation Apparatus for Cardiac Data,* issued to Adams and Kroll in 1994, wherein the data accumulated in a limited capacity memory implanted device is telemetered out to a larger capacity, external data recorder. The accumulated data is also forwarded to a clinic

devices. If the information about inventory status at the implanting institution, such as the implantation of a medical device (a reduction in inventory) could be telemetered to the manufacturing site, the manufacturer could then build an identical device to replace the recently implanted device—a process called "build-to-order".

Build-to-Order manufacturing and control systems are well known to those familiar with the art. Such systems were pioneered by Dell USA, when the company's founder, as far back as 1985, began to manufacture and assemble computers to meet the needs of the user customer. This method of manufacturing and delivery of the product has been further enhanced by allowing potential customers to specify the exact type of desktop or laptop computer s/he wishes to purchase. Overhead, in the form of an outlet store with its accompanying sales personnel and incremental costs, are non-existent. As a result, Dell USA is able to consistently provide quality products at consistently lower costs, as compared to its competition. Dell USA holds well over 200 patents, many of which relate directly to the design and implementation of its build-to-order process. To mention but two such patents, we may cite U.S. Patent Nos. 5,894,571 *Process for Configuring Software in a Build-to-Order Computer System*, issued to O'Connor, and 5,995,757 *Software Installation and Testing for a Build-to-Order Computer System*, both hereby referenced in their totality.

Another model that may be cited comes from IBM that holds U.S. Patent No. 6,078,900 in June, 2000, *Method for Estimating Stock Levels in Production-Distribution Networks with Inventory Control*, issued to Amberg et al., also referenced herein in its totality. That invention provides computer software for business management and a computer implemented method for estimating stock levels in production-distribution networks with inventory control.

There are many similarities between the computer industry and the medical device industry. Thus, it should be possible to adapt and improve upon these well-known build-to-order systems and methods to fit the needs of the medical device industry.

Medical device industries are growing at a rapid rate with a corresponding rapid growth and change in their production processes. At present, the distribution of these products requires multiple stockholding points. One of the great challenges in the medical device environment is a company's ability to meet end-customer demand for an adequate

of the patient to be implanted the next day, or later in the day on which the request is made. What is to be done then? Usually a call is made to the manufacturer's local business office that may or may not have the exact model on hand. If so, someone has to bring it to the institution. This may involve many miles depending on the location of the business office relative to the medical institution. If this device is not available at the local business office, a call will be made to the manufacturer's central office or to the manufacturing facility. In such cases and even when Herculean efforts take place, the device will not usually arrive at the institution in time for the original scheduled implant. Often the implant must be postponed for several days. This is the primary issue that the present invention addresses.

A secondary issue that must be addressed occurs during those times when the device manufacturer is introducing a new product. The manufacturing facility must have on hand a rather large number of newer devices which the physicians and institutions will request for use upon approval for implant is received from an approving agency such as the FDA in the U.S.A. and other such agencies in Europe and Japan. Yet, until approval is given, none of the newer devices may be implanted. Only those that were previously approved may be implanted. If the approval is delayed for one reason or another, the manufacturer must maintain two inventories, one of the older and one of the newer product lines. In such cases, when approval is finally granted and because the physicians usually wish to make use of the newer technology, the manufacturer must usually retrieve the older product inventory and dispose of it in some way or other, usually at an economic loss to the manufacturer which, in turn, can bring about a subsequent increase in cost to the government, insurance payer, or patient.

The key challenge that the medical device industry must face is to determine where and in what quantities to hold safety stock in the network so as to protect against uncertainties, and to ensure that target customer service levels are met. Aggressive service requires significant inventory planning. Today, the determination of inventory levels is localized and often ad hoc, and not based on an analysis of optimal levels and deployment. As a result, the business impact, in terms of the trade-off between inventory investment and customer serviceability or delinquency, is far from optimal.

not limited to—implantable pacemakers, cardioverter-defibrillators, neurological stimulators, leads, drug delivery systems, lead adapters, lead repair kits, etc. On the other hand, this invention may be used to control and manage manufacturing planning and scheduling, forecasting product consumption, purchasing device components, inventory control at the manufacturing facility, vendor management, material tracking, capacity planning, distribution and shipping of finished product, etc.

The required data, for example that a specific device with its associated lead(s) , has been implanted may be transferred by the programmer to the Information Network, described in the '976 patent. These data may be downloaded on a real time basis or on a daily basis, usually at night. The Information Network will then summarize these data on a daily basis and issue a built order to replenish the stock that was "consumed" at implant for the specific implanting institution. Specifically, the device type, model number, serial number, name of the implanting physician, the name of the sales representative, the name of the implanting institution are automatically downloaded to the Information Network through the programmer, as substantially described in U.S. Patent No. 5,345,362 and Des. 358,583 by Winkler, both of which are incorporated by reference in their entirety. These data, when received, would in turn automatically initiate a "build-to-order" replenishment to match and replace the device(s) implanted at that institution.

Although the intention of this process is to have a very quick turnaround time, e.g., a total of two days from notification of implant, building the product in an automated assembly line, and delivery of the product, it is also possible that the status of the product build could be made available to all interested parties (purchase agent, physician, hospital administrator, sales rep, etc.) on an ongoing basis. Other benefits would include substantial cost savings in manufacturing, reduced product cycle times, reduced obsolescence, reduced inventories at all points in the product delivery chain, and so on. This process will minimize inventory issues for the account, as well as for the manufacturer. In addition it will make it easier to ramp up for the introduction of a new product while, at the same time ramping down the build of the old product. "Phase out" should be much simpler and quicker. With the attainment of these benefits, the costs to the implanting institution can also be controlled and reduced significantly.

should be no difficulty in establishing communications between the implanted device and the programmer. In this situation, the programmer determines location and details relevant to the device communicates those data via a cellular telephone system link or a satellite based telecommunications link if the patient is outside the range of a cellular link or subscribes only to the satellite-based link.

FIG. 1 is an illustration of an implantable medical device system adapted for use in accordance with the present invention. The medical device system shown in FIG. 1 includes an implantable device 10—a pacemaker for illustration purposes—that has been implanted in a patient 12. In accordance with conventional practice in the art, pacemaker 10 is housed within a hermetically sealed, biologically inert outer casing, which may itself be conductive so as to serve as an indifferent electrode in the pacemaker's pacing/sensing circuit. One or more pacemaker leads, collectively identified with reference numeral 14 in FIG. 1 are electrically coupled to pacemaker 10 in a conventional manner and extend into the patient's heart 16 via a vein 18. Disposed generally near the distal end of leads 14 are one or more exposed conductive electrodes for receiving electrical cardiac signals and/or for delivering electrical pacing stimuli to heart 16. As will be appreciated by those of ordinary skill in the art, leads 14 may be implanted with their distal end(s) situated in the atrium and/or ventricle of heart 16.

Although the present invention will be described herein in an embodiment which includes a pacemaker, those of ordinary skill in the art having the benefit of the present disclosure will appreciate that the present invention may be advantageously practiced in connection with numerous other types of implantable medical device systems, and indeed in any application in which it is desirable to provide a communication link between two physically separated components.

Also depicted in FIG. 1 is an external programming unit 20 for non-invasive communication with implanted device 10 via uplink and downlink communication channels, to be hereinafter described in further detail. Associated with programming unit 20 is a programming head 22, in accordance with conventional medical device programming systems, for facilitating two-way communication between implanted device 10 and programmer 20. In many known implantable device systems, a programming head such as that depicted in FIG. 1 is positioned on the patient's body over the implant site of

conditions is rising due to the growth in the elderly population. For these reasons, the need for ensuring the availability of an adequate inventory of pacemakers within the implanting hospital is vital and this need can be fulfilled with medical telemetry equipment such as that used in the programmer depicted in FIG. 2

Referring to FIG. 2, programmer 20 comprises an outer housing 60, which is preferably made of thermal plastic or another suitably rugged yet relatively lightweight material. A carrying handle, designated generally as 62 in FIG. 2, is integrally formed into the front of housing 60. With handle 62, programmer 20 can be carried like a briefcase.

An articulating display screen 64 is disposed on the upper surface of housing 60. Display screen 64 folds down into a closed position (not shown) when programmer 20 is not in use, thereby reducing the size of programmer 20 and protecting the display surface of display 64 during transportation and storage thereof. Stylus 24 is used for data entry and/or control of programmer 20.

A floppy disk drive is disposed within housing 60 and is accessible via a disk insertion slot (not shown). A hard disk drive is also disposed within housing 60, and it is contemplated that a hard disk drive activity indicator, (e.g., an LED, not shown) could be provided to give a visible indication of hard disk activation.

As would be appreciated by those of ordinary skill in the art, it is often desirable to provide a means for determining the status of the patient's conduction system. Normally, programmer 20 is equipped with external ECG leads. These leads may be rendered redundant if the implanted device is equipped with a "subcutaneous electrode array" as described in the filed application 09/749,169, *Leadless Fully Automatic Pacemaker Follow-Up*, by Combs et al., filed December 12, 2000.

Programmer 20 is equipped with an internal printer (not shown) so that a hard copy of a patient's ECG or of graphics displayed on the programmer's display screen 64 can be generated. Several types of printers, such as the AR-100 printer available from General Scanning Co., are known and commercially available.

In the perspective view of FIG. 2, programmer 20 is shown with articulating display screen 64 having been lifted up into one of a plurality of possible open positions such that the display area thereof is visible to a user situated in front of programmer 20. Articulating display screen is preferably of the LCD or electro-luminescent type, characterized by

forwarded to that portion of the network computer related to new build orders for manufacturing, which relates to FIG. 4.

Turning our attention now to FIG. 4, we see the various steps used during the manufacturing process to ensure that the recently implanted ICD (using the example mentioned above) is replaced as quickly as possible. Once an implant has taken place at a particular institution the data is available to the Information Network 60 (see FIG. 3), that same network, which is constantly monitoring the "build-to-order" status 72. The network periodically determines whether a device needs to be built 70 for this particular institution. If No, then it continues to monitor for an implant. If Yes, then the implant data is downloaded to the manufacturing database 74. This includes all pertinent data relative to the implanted device. Specifically, these data will include the device type, model number, serial number, name of the implanting physician, the name of the sales representative, and the name of the implanting institution. These data, when received, will automatically initiate a "build-to-order" replenishment to match and replace the standard device(s) implanted at that institution.

Once the order is made, a comparison is made to assess whether the build will meet the planned inventory 76. In addition, the manufacturing database will determine whether all components required to complete the build are available 78 at the factory site located nearest to the implanting institution. If components are available, that factory site is selected and scheduled to complete the build 80. If components are not available, the manufacturing database issues an automatic component supplier order 94. The required components are noted and shipped by the supplier(s) 92 to the manufacturing site.

Initiating build 82 with available components or those delivered from the supplier results in building and assembly of the "standard" device, which will replace the implanted device in the inventory of the implanting institution. The implantable device is tested at various stages in the manufacturing process 84 and will undergo final testing prior to packaging 86 and sterilization. Finally, the device is shipped 88 to the implanting institution 90 for restocking in their inventory.

During this whole process, the purchasing agent and/or hospital administrator is able to discern exactly the stage that the device being manufactured has reached. Such information will be available on the Information Network that is accessed via the Internet

What is claimed is:

1. A medical device manufacturing and supply information management system comprising:

a Web-enabled information network;

a programmer; and

at least one implanted medical device, deployed from a known source, said Web-enabled information network being in bi-directional data communications scheme with the programmer, and the programmer being in data communication with said implanted medical device.

2. The system of claim 1 wherein said Web-enabled information network implements a Global Communications and Monitoring system (GCMS).

3. The system of claim 1 wherein said Web-enabled information network includes one of a satellite based telecommunications link and a cellular link.

4. The system of claim 1 wherein said programmer is implemented to interface between the medical device and the Web-enabled information network via the bi-directional data communications scheme to store manufacturing information in addition to information about the at least one implanted medical device.

5. The system of claim 1 wherein said at least one implanted medical device includes one of a new implant or an old implant needing an upgrade.

6. The system of claim 1 wherein said known source includes at least one of a manufacturing center, hospital, sales office, distributor having data communications with the Web-enabled information network.

7. A medical device inventory and production control system synchronous with various phases of product manufacturing for standard, customized and newly approved, modified/redesigned devices and to stock various consumption hubs including hospitals,

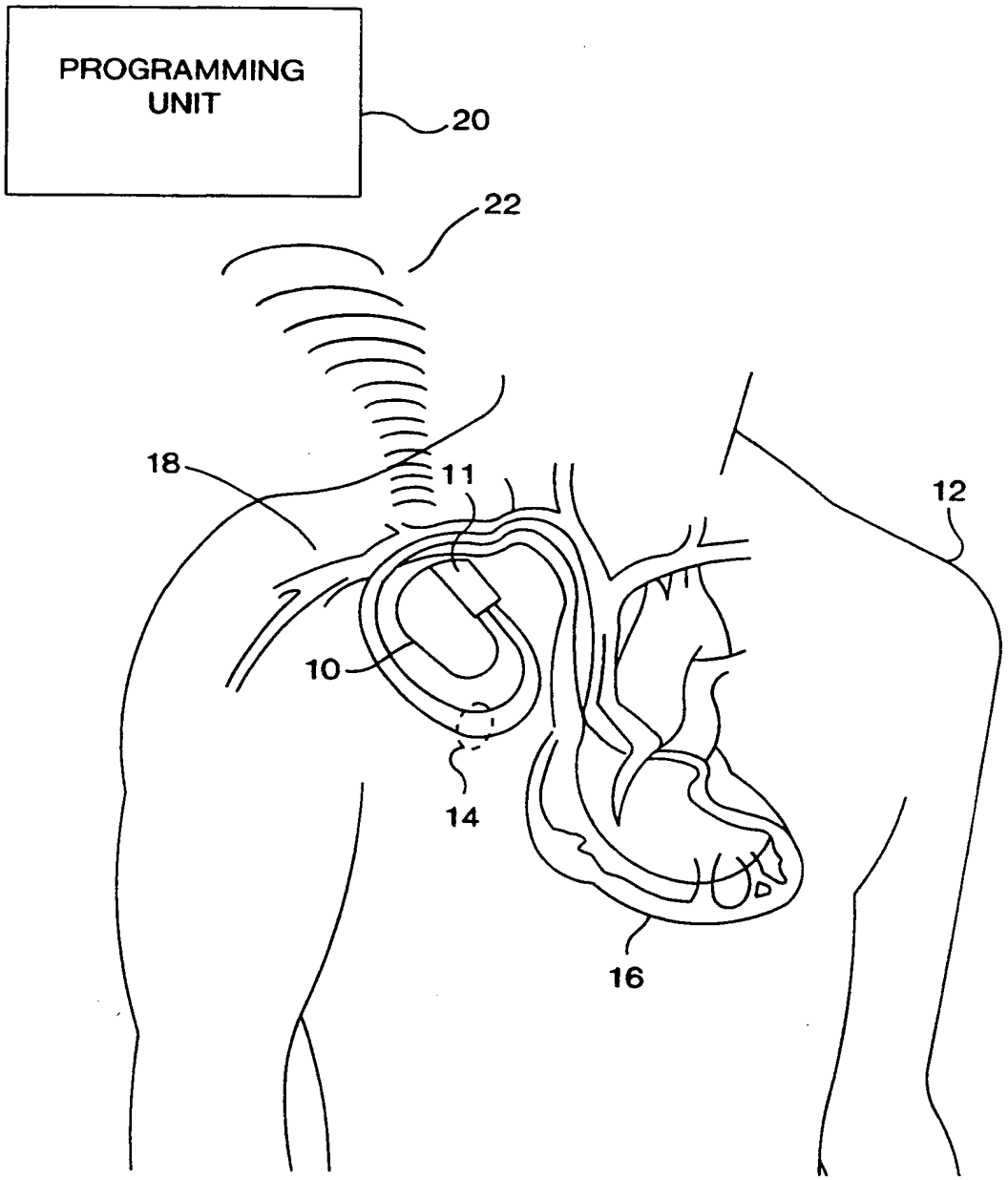

FIG. 1

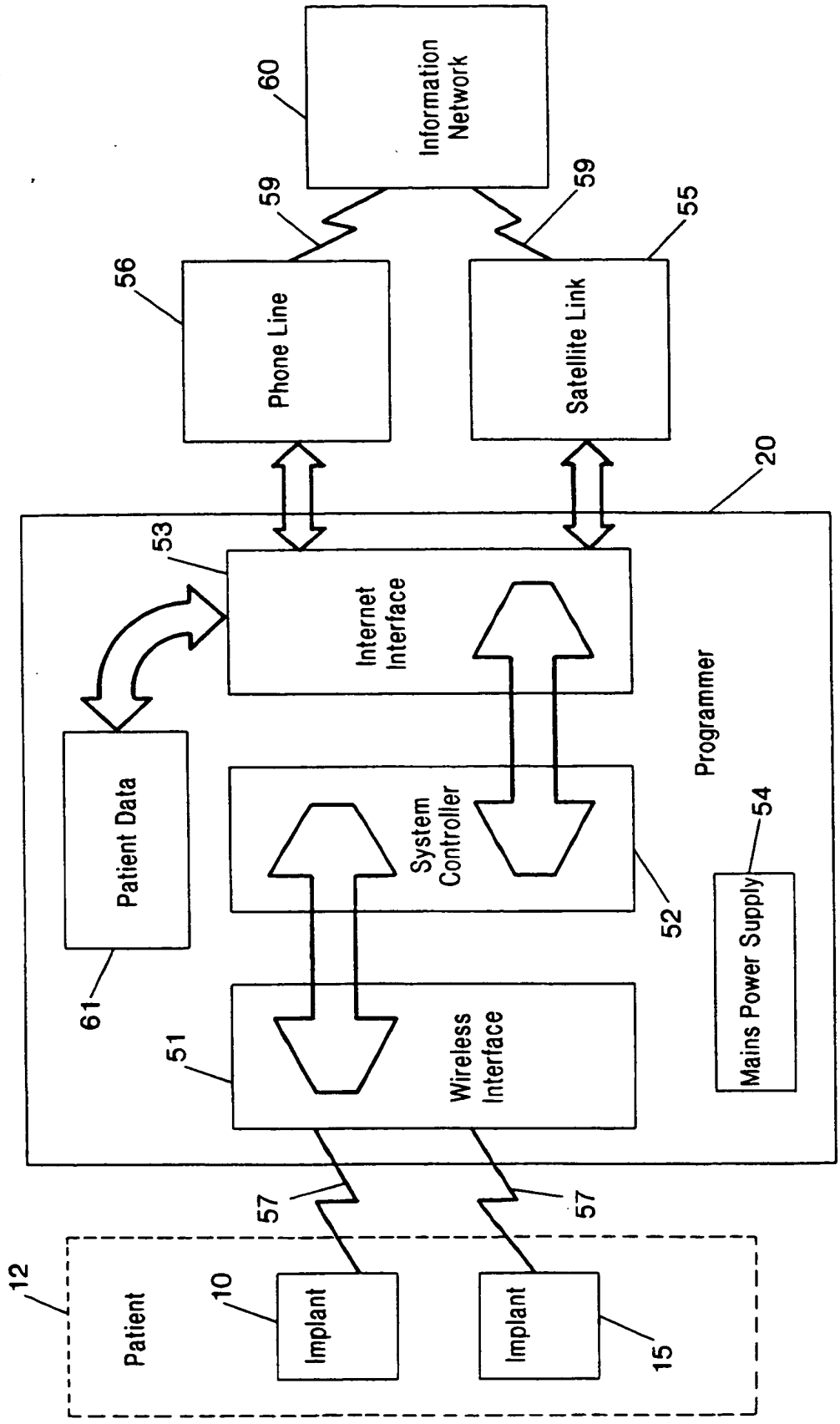

FIG. 3

INTERNATIONAL SEARCH REPORT

Int tional Application No
PCT/US 01/03417

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N1/372 A61B5/00 G06F17/60

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61N A61B G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	US 5 855 609 A (KNAPP TERRY R) 5 January 1999 (1999-01-05) column 6, line 38-67	1,6-8

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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Date of the actual completion of the international search	Date of mailing of the international search report
11 June 2001	22/06/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Grossmann, C.

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

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